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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,903	09/17/2003	Stephen J. O'Connor	5062C1	8521
35969	7590	06/25/2004	EXAMINER	
JEFFREY M. GREENMAN BAYER PHARMACEUTICALS CORPORATION 400 MORGAN LANE WEST HAVEN, CT 06516				COPPINS, JANET L
ART UNIT		PAPER NUMBER		
		1625		

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	10/666,903	
Examiner	O'CONNOR ET AL.	
Janet L. Coppins	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-30 pending in the instant application.

1. The instant application is a continuation of U.S. application 10/131,448, which has been found allowable in its amended form, i.e. wherein Ar is pyridine. The '448 application had initially been restricted into nine Groups, therefore the Examiner has applied the same restriction requirement, as follows:

Election/Restrictions

2. The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30 (in part), drawn to compounds, pharmaceutical compositions, methods of use, and processes of preparation according to Formula I, wherein Ar is a 6-membered heterocycle containing 1 N atom (pyridine), and the remaining variables are as defined in claim 1, classified in multiple subclasses of class 546. A further election of a single disclosed species will be required if this Group is elected.

II. Claims 1-30 (in part), drawn to compounds, pharmaceutical compositions, methods of use, and processes of preparation according to Formula I, wherein Ar is phenyl, and the remaining variables are as defined in claim 1, classified in multiple subclasses of class 549. A further election of a single disclosed species will be required if this Group is elected.

Art Unit: 1625

III. Claims 1-30 (in part), drawn to compounds, pharmaceutical compositions, methods of use, and processes of preparation according to Formula I, wherein **Ar** is a 6-membered heterocycle containing 2 or more N atoms (pyrimidines, triazines, etc) and the remaining variables are as defined in claim 1, classified in multiple subclasses of class 544. A further election of a single disclosed species will be required if this Group is elected.

IV. Claims 1-30 (in part), drawn to compounds, pharmaceutical compositions, methods of use, and processes of preparation according to Formula I, wherein **Ar** is a 5-membered heterocycle containing only N atoms (pyrrole, pyrazole, triazole, etc), and the remaining variables are as defined in claim 1, classified in multiple subclasses of class 548. A further election of a single disclosed species will be required if this Group is elected.

V. Claims 1-30 (in part), drawn to compounds, pharmaceutical compositions, methods of use, and processes of preparation according to Formula I, wherein **Ar** is a 5-membered heterocycle containing only O and/or S atoms (furan, thiophene, etc) and the remaining variables are as defined in claim 1, classified in multiple subclasses of class 549. A further election of a single disclosed species will be required if this Group is elected.

VI. Claims 1-30 (in part), drawn to compounds, pharmaceutical compositions, methods of use, and processes of preparation according to Formula I, wherein **Ar** is a 5-membered heterocycle containing N atoms, O atoms, and/or S atoms (oxazole, thiazole, etc) and the remaining variables are as defined in claim 1, classified in multiple subclasses of class 548. A further election of a single disclosed species will be required if this Group is elected.

VII. Claims 1-30 (in part), drawn to compounds, pharmaceutical compositions, methods of use, and processes of preparation according to Formula I, wherein **Ar** is a 6-

membered heterocycle containing only O atoms, and/or S atoms (pyran, thienyl etc) and the remaining variables are as defined in claim 1, classified in multiple subclasses of class 549. A further election of a single disclosed species will be required if this Group is elected.

VIII. Claims 1-30 (in part), drawn to compounds, pharmaceutical compositions, methods of use, and processes of preparation according to Formula I, wherein Ar is a 6-membered heterocycle containing N atoms, O atoms, and/or S atoms (morpholine, thiazine, oxathiazine etc) and the remaining variables are as defined in claim 1, classified in multiple subclasses of class 544. A further election of a single disclosed species will be required if this Group is elected.

IX. Claims 1-30 (in part), drawn to compounds, pharmaceutical compositions, methods of use, and processes of preparation according to Formula I, wherein Ar is a fused ring system containing phenyl, and the remaining variables are as defined in claim 1, classified in classes 544-549. A further election of a single disclosed species will be required if this Group is elected.

3. In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other members obvious under 35 U.S.C. 103.

Art Unit: 1625

4. Where an election of any one of Groups I-IX is made, an election of a single disclosed compound (in the specification) is further required, including an exact definition of each substituent on the base molecule (formula I), wherein a single member at each substituent group or moiety is selected. For example, the base molecule has the substituent R, wherein R is any one of hydroxy, oxo, halogen, alkyl, CN, NO₂, etc., then the Applicant must select a single substituent and each subsequent variable position. The scope of an independent invention will encompass all compounds within the scope of the above-identified Group that the elected compound falls within (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected species, as defined by the above Groups and common classification. Should applicant traverse on the ground that the compounds are not patentable distinct, applicant should submit evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

All compounds falling outside the class(es) and subclass(es) of the selected compound and other compounds encompassed by the elected Group above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R.

1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rationale Establishing Patentable Distinctiveness Within Each Group

6. Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions (Groups), i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, whereas chemical that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Applications of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir, 1984), chemical structures are patentably

distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

7. The Inventions of Groups I-IX are related as mutually exclusive species in the Markush group of Formula (I). Inventions I-IX are distinct and independent from each other because the compounds differ structurally, one from the other as defined by the different variables recited in claim 1. For example, within formula I, the variable R alone has many separate, generic possibilities, including distinct carbocyclic or heterocyclic ring systems, which cannot be said to belong to the same class and subclass of chemical classification.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the Examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
June 21, 2004

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